

NOV - 8 2004

K 041959

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

### SYNERON MEDICAL Ltd. POLARIS DS / Comet

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

**Submitter:** Syneron Medical Ltd., Sultam Industrial park, P.O.B. 550,  
Yokneam Elite 20692, Israel.  
Tel. +972-4-909-7424 ext. 7604, Fax +972-4-909-7417

**Name of the Device:** Polaris DS / Comet

**Predicate Devices:** The Polaris DS /Comet is substantially equivalent to a combination of four laser powered surgical instruments (21 CFR 878.4810, procode GEX): Polaris DS, manufactured by Syneron Medical Ltd. and subject of K024064. Polaris WR, manufactured by Syneron Medical Ltd. and subject of K031671. LightSheer, manufactured by Lumenis Inc. and subject of K003614. Mythos 500, manufactured by Msq Ltd. and subject of K030805

**Device Description:** The Polaris DS / Comet is a device indicated for hair removal, permanent hair reduction. The Polaris DS is intended for use on all skin types, (Fitzpatrick skin type I-VI), including tanned skin. The Polaris DS / Comet treatment is based on the principle of *selective (electromagnetic) thermolysis*. According to this principle, parameters of optical and RF energy (spectrum, exposure duration and energy density) are chosen and optimized to selectively damage to the hair follicle without damaging the surrounding tissues.

The Polaris DS is intended for use in dermatology for hair removal, permanent hair reduction. The Polaris DS is intended for use on all skin types, (Fitzpatrick skin type I-VI), including tanned skin.

Based upon an analysis of the overall performance characteristic for the device, Syneron Medical Ltd. believes that no significant differences present. Therefore the Polaris DS / Comet should raise no new issues of safety or effectiveness.

July 19 2004

Amir Waldman

Date

Dr. Amir Waldman,  
Director regulatory affairs  
Syneron medical Ltd.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Dr. Amir Waldman  
Director, Regulatory Affairs  
Syneron Medical Ltd.  
Sultam Industrial Park  
P.O.B 550 Yokneam Elite  
20692, Israel

Re: K041959

Trade/Device Name: Polaris DS / Comet  
Regulation Number: 21 CFR 878.4810, 21 CFR 878.4400  
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology, Electrosurgical cutting and coagulation device and accessories

Regulatory Class: II  
Product Code: GEX, GEI  
Dated: October 21, 2004  
Received: October 25, 2004

Dear Dr. Waldman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

*Miriam C. Provost*  
for

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known) K 041959.

Device Name Polaris DS / Comet.

**Indications For Use:**

The Polaris DS / Comet is indicated for hair removal, permanent hair reduction. The Polaris DS / Comet is intended for use on all skin types, (Fitzpatrick skin type I-VI), including tanned skin.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over The Counter Use       

(Optional Format 1-2-96)

Miriam C. Provost  
(Division Sign-Off)  
Division of General, ~~Reproductive~~  
and Neurological Devices

510(k) Number K041959